IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

ROBERT L. APTER, M.D., FACEP; MARY TALLEY BOWDEN, M.D.; and PAUL E. MARIK, MBBCh, M.MED, FCCM, FCCP, *Plaintiffs*, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; FOOD AND DRUG ADMINISTRATION; and ROBERT M. CALIFF, M.D., MACC, in his official capacity as Commissioner of Food and Drugs, *Defendants.*	)	No. 3:22-cv-184

PLAINTIFFS' OPPOSITION TO DEFENDANTS' RENEWED MOTION TO DISMISS THE AMENDED COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTRODUCTION

The U.S. Food and Drug Administration ("FDA") is a gatekeeper with authority to "approve" when a drug can be introduced to the market in the United States and what labeling it can use. Once approved, "the FDA does not restrict physicians from prescribing an otherwise FDA-approved drug for an off-label use." *U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 (5th Cir. 2017). Off-label use is not only "common," but it may "in many cases . . . represent the standard of care in the industry." *Id.* (cleaned up).

The FDA also cannot direct or advise how doctors should prescribe, or patients should take, an approved drug. Those decisions fall within the scope of the doctor-patient relationship. Attempts by the FDA to influence or intervene in the doctor-patient relationship constitute interference with the practice of medicine, the regulation of which is—and always has been—reserved to states.

The FDA exceeded its authority by repeatedly issuing public directives not to use ivermectin for COVID-19, even though the drug remains fully approved for human use. This includes a publication titled, "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," Ex.1,[1] to which the FDA linked in a letter to the Federation of State Medical Boards and which on its face seeks to interfere with a decision that is preserved for the doctor-patient relationship. Other FDA directives are even more blunt, stating: "Q: Should I take ivermectin to prevent or treat COVID-19? A: No," Exs.2, 3; and "You are not a horse. You are not a cow. Seriously, y'all. Stop it," Ex.4; and "You are not a horse.

[1] Exhibits ("Ex.") 1–28 are attached to the Amended Complaint. Exhibits 29–30 are submitted with this brief.

Stop it with the #Ivermectin. It's not authorized for treating #COVID," Ex.6. The FDA has never withdrawn any of these publications and almost all remain active on official FDA platforms, some for nearly three years.

Plaintiffs in this case—Dr. Robert L. Apter, Dr. Mary Talley Bowden, and Dr. Paul E. Marik—sued the FDA[2] for non-monetary equitable relief, alleging its actions were ultra vires and violated the Administrative Procedure Act ("APA"). This Court dismissed those claims as barred by sovereign immunity, but the Fifth Circuit held on appeal that the ultra vires claim could proceed. The Fifth Circuit explained that the "FDA is not a physician" and has not identified "any authority that allows it to issue recommendations or give medical advice." *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 583 (5th Cir. 2023). The FDA "has not offered even a 'colorable basis'" for its actions. *Id.* at 588. While "[i]t has authority to inform, announce, and apprise," it cannot "endorse, denounce, or advise," and "[e]ven tweet-sized doses of personalized medical advice are beyond FDA's statutory authority." *Id*. at 595. The Court therefore concluded that Plaintiffs "have plausibly alleged that FDA's [actions] fell on the wrong side of the line between telling *about* and telling *to*," so sovereign immunity does not bar their ultra vires claim. *Id.* at 595.

On remand, the FDA renewed a previous motion to dismiss for lack of standing, arguing that Plaintiffs have not suffered concrete injuries that are fairly traceable to the FDA and can be remedied by a favorable decision. The FDA is wrong. Plaintiffs have suffered interference with their practice of medicine and the doctor-patient relationship,

[2] Plaintiffs sued the FDA, the Department of Health and Human Services ("HHS"), the Secretary of HHS, and the Commissioner of Food and Drugs (collectively, "the FDA").

economic harm, reputational harm, and increased exposure to malpractice liability, and have been subject to disciplinary proceedings and forced resignations, all of which clearly trace to the FDA's campaign against ivermectin and would be remedied by equitable relief.

Common sense confirms that the only reason the FDA would issue its ivermectin publications in the first place is because of the predictable and intended effects they would have on healthcare professionals, regulatory boards, hospitals, patients, and the broader public to stop the use of ivermectin to treat COVID-19—precipitating the very harms Plaintiffs have experienced. The FDA plainly desired that end, or the entire endeavor would have been pointless. But now the FDA argues that its actions had no effect, lacked even plausible traceability to their intended outcome, and cannot be remedied.

Judges "are not required to exhibit a naiveté from which ordinary citizens are free." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575–76 (2019). The FDA cannot use unlawful means to accomplish its objectives and then wash its hands of the consequences.

The motion to dismiss should be denied.

BACKGROUND

I. FDA's Statutory Authority

The FDA has authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to approve a drug "for introduction into interstate commerce" if the agency determines the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," and there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(a), (d).

Once approved, doctors are free to prescribe these drugs for "off-label" purposes.

"Off-label prescription of drugs is common, with as many as forty percent of all prescriptions issued involving off-label use." Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 Penn. St. L. Rev. 41, 46 (2005). Their use "can be a source of innovation, and in some settings may represent the standard of care." Donna T. Chen et al., *U.S. Physician Knowledge of the FDA-Approved Indications and Evidence Base for Commonly Prescribed Drugs: Results of a National Survey*, 18 Pharmacoepidemiology & Drug Safety 1094, 1094 (2009) (footnotes omitted). Regarding off-label prescriptions, the FDA has even acknowledged that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment." Food & Drug Admin., *"Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices* (Jan. 1998), http://tinyurl.com/4etfhhpy.

Generally, the FDA cannot prohibit, direct, or advise against the off-label uses of approved human drugs. Nothing in the FDCA gives the agency that authority. *Ass'n of Am. Physicians & Surgeons* ("*AAPS*") *v. FDA*, 13 F.4th 531, 534 (6th Cir. 2021) ("Although the [FDCA] regulates a manufacturer's distribution of drugs, it does not go further by regulating a doctor's practice of medicine. . . . It instead leaves the regulation of doctors to the states."); *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 400 (D.C. Cir. 2021) ("Choosing what treatments are or are not appropriate for a particular condition is at the heart of the practice of medicine."). When Congress has authorized the FDA to limit particular uses of an approved drug, Congress has done so explicitly. *E.g.*, 21 U.S.C.

§ 333(e) (restricting off-label use of "human growth hormone"). It is undisputed that Congress has not done so here.

The FDA thus cannot take actions, including pressure campaigns and jawboning, that "interfere" with "the practice of medicine, which is the exclusive realm of individual states." *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006); *see also, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 350 (2001) ("[T]he FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals."); *AAPS*, 13 F.4th at 534; *Judge Rotenberg*, 3 F.4th at 400.

As a result, once a drug has been approved by the FDA for human use, appropriate healthcare professionals can prescribe or dispense the drug off-label when done for a medical purpose within the scope of a doctor-patient relationship. *See, e.g.*, *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) ("Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses."); *Planned Parenthood Cincinnati Region*, 444 F.3d at 505 ("Absent state regulation, once a drug has been approved by the FDA, doctors may prescribe it for indications and in dosages other than those expressly approved by the FDA. . . . Off-label use does not violate federal law or FDA regulations[.]"); *Wash. Legal Found. v. Henney,* 202 F.3d 331, 333 (D.C. Cir. 2000) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA."). The FDA cannot wade into the debate over whether certain drugs can or should be used for specific purposes. Its role is a gatekeeper,

not regulator, of the practice of medicine.

II. FDA Campaign Against Ivermectin

On March 5, 2021, the FDA published "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" on its website. Ex.19. The title of the publication states an official FDA position that ivermectin should not be used for the treatment or prevention of COVID-19. *Id.* Nowhere did this publication acknowledge that doctors can lawfully prescribe ivermectin for that use, instead stating only that "[i]f you have a prescription for ivermectin *for an FDA-approved use*, get it from a legitimate source and take it exactly as prescribed." *Id.* at 2. This incorrectly conveyed that ivermectin can only be prescribed and used for FDA-approved purposes. Ironically, the FDA took this action notwithstanding an admission that the agency "ha[d] not reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19." *Id.*

The FDA later amended "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" to state that "[i]f your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed," removing "for an FDA-approved use." Ex.1, at 2. But that "trailing qualifier does not lessen the opening instruction's imperative character." *Apter*, 80 F.4th at 589.

The FDA has also published an Ivermectin FAQ, entitled "COVID-19 and Ivermectin Intended for Animals." Ex.2. The Ivermectin FAQ begins with, "Q: Should I take ivermectin to prevent or treat COVID-19?" and flatly answers that question, "A: No." *Id.* It continues that "[w]hile there are approved uses for ivermectin in people and animals, it is not approved for the prevention or treatment of COVID-19. You should not take any

medicine to treat or prevent COVID-19 unless it has been prescribed to you by your health care provider and acquired from a legitimate source." *Id.* None of this changes the FDA's unequivocal direction that ivermectin should not be used for COVID-19 and the clear message that doctors should not (and possibly cannot) prescribe it for that use.

The FDA similarly maintains another COVID-19 FAQ that asks, "Q: Should I take ivermectin to prevent or treat COVID-19?" and answers that question, "A: No." Ex.3. The COVID-19 FAQ continues that "[w]hile there are approved uses for ivermectin in people and animals, it is not approved for the prevention or treatment of COVID-19," followed by a link to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *Id.*

On August 21, 2021, the FDA tweeted, "You are not a horse. You are not a cow. Seriously, y'all. Stop it." Ex.4. The tweet displayed the title of FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and linked to that publication. The FDA posted the same image and message to LinkedIn and Facebook. Ex.5. All three publications unequivocally direct the public not to use ivermectin for COVID-19. The August 21, 2021 tweet was viewed by over 24 million people in two days—not including the millions more who saw the tweet reproduced on other platforms or in mainstream media—quickly becoming the most viewed tweet in FDA history. Ex.20.

Also on August 21, 2021, the FDA posted to Instagram a picture of a horse with the caption, "You are not a horse. Stop it with the #Ivermectin. It's not authorized for treating #COVID." Ex.6. The post misleadingly depicts ivermectin as a horse medication not approved for human use and unequivocally directs the public not to use it for COVID-19.

The FDA celebrated its successful messaging as part of a "new engagement

strategy" to influence the public. Ex.20. Erica Jefferson, Associate Commissioner for External Affairs, explained that the FDA saw this as an "opportunity to remind the public" of the FDA's position on ivermectin, creating "a unique viral moment" where the FDA could "reach the 'everyday' American . . . in a time of incredible misinformation." Ex.21, at 5–6. She similarly expressed her satisfaction about the number of people who viewed the tweet: "The numbers are racking up and I laughed out loud." *Id.* at 4.

The FDA went further still, sending a letter to the Federation of State Medical Boards and National Association of Boards of Pharmacy to further influence medical practice. It warned against using ivermectin for COVID-19 and included a link to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." Ex.22.

The FDA's "new engagement strategy" resulted in its foreseeable and intended effect of interfering with the use of ivermectin to treat COVID-19. The FDA was delighted to see media outlets parrot its message, referring to ivermectin as "horse dewormer" and "horse paste." Ex.21. As intended, others pushed the narrative with headlines like "Say 'Neigh' to Ivermectin" and "You Are Not a Horse." *Id.*

Individual healthcare professionals even joined the refrain, citing the FDA and publicly labeling those who prescribe ivermectin, including Plaintiffs, as quack doctors practicing veterinary medicine on humans. *See* Exs.23–24.

Again, following the FDA's lead, the American Medical Association ("AMA"), American Pharmacists Association ("APhA"), and American Society of Health-System Pharmacists ("ASHP") quickly issued a joint statement "strongly oppos[ing] the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical

trial," and pointed to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" as part of their justification. Ex.25. This joint statement was issued just 11 days after the FDA's "Stop it" tweet. State pharmacy boards likewise issued statements on dispensing ivermectin, which directly linked to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *See, e.g.*, Ex.26. And hospitals also started relying on the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and August 21, 2021, tweet—even reproducing the tweet in court filings—to justify prohibiting the use of ivermectin to treat patients, regardless of whether the drug was prescribed by a doctor. Ex.12, at 5; Ex.27, at 8–9, 21.

Even courts have relied on the FDA's actions to decide cases involving ivermectin, including as persuasive evidence about the effectiveness of the drug and appropriate standard of care. *See, e.g.*, *Shoemaker v. UPMC Pinnacle Hosps.*, 283 A.3d 885, 895 (Pa. 2022); *Smith v. West Chester Hosp.*, LLC, 2021 WL 4129083, at *1, 2, 4 (Ohio Ct. Com. Pl. Sept. 6, 2021); *DeMarco v. Christiana Care Health Servs., Inc.*, 263 A.3d 423, 435 (Del. Ch. 2021); *Abbinanti v. Presence Cent. & Suburb. Hosps. Network*, 2021 IL App. (2d) 210763, ¶ 10 (2021); *see also Gahl v. Aurora Health Care, Inc.*, 977 N.W.2d 756, 762–63 (Wis. Ct. App. 2022). Indeed, courts have looked to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" to determine "deviation from accepted medical practices," which "is an essential element of medical malpractice." *D.J.C. for D.A.C. v. Staten Island Univ. Hosp.-Northwell Health*, 157 N.Y.S.3d 667, 673 (2021).

"All told, the [Twitter posts]—and particularly ["Why You Should Not Use Ivermectin to Treat or Prevent COVID-19"]—saw citations in newspapers, magazines,

digital media outlets, medical and professional advisories, legal complaints, and judicial opinions across the Nation." *Apter*, 80 F.4th at 585.

On April 26, 2022, the FDA continued its relentless campaign, again pushing its narrative that ivermectin is only for animal use and advising the public not to use it for COVID-19. The tweet read, "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19." Ex.7. The tweet again displays the title of "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and links to that publication. *Id.*[3]

III. Procedural History

Plaintiffs filed suit in the Southern District of Texas on June 2, 2022, and amended their complaint on August 8, 2022, alleging the FDA acted ultra vires and violated the APA. ECF.Nos.1, 12. On August 26, 2022, the FDA filed a motion to dismiss under Federal Rules of Civil Procedure 12(b)(1) and (6), arguing that Plaintiffs lack constitutional standing to pursue their claims and invoking sovereign immunity. ECF.No.25. This Court

[3] The FDA is wrong to frame these actions as only a concerned response to "multiple reports of patients who required medical attention, including for hospitalization, after self-medicating with ivermectin products intended for animals." R-MTD.1. *First*, the article "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" was initially published on March 5, 2021, predating the reports about use of animal ivermectin in August 2021. *Second*, the FDA was still using the "horse paste" trope as late as April 26, 2022, long after any concern would have abated from handful of earlier reports about animal-ivermectin use. *Third*, internal correspondence from the FDA confirms the agency's goal was to use the situation as an "opportunity to remind the public of [its] own warnings for ivermectin," Ex.21, at 5, and try a "new engagement strategy," Ex.20, which explains its dramatic response to a mere four people using animal ivermectin in a country of over 330 million people, *see* Ex.21, at 1–3. And *fourth*, the FDA's statements repeatedly referenced ivermectin—*not* "animal ivermectin."

dismissed the claims as barred by sovereign immunity. ECF.No.45.

The Fifth Circuit reversed as to Plaintiffs' ultra vires claim, holding that the FDA "has not offered even a 'colorable basis'" for its actions, and "[e]ven tweet-sized doses of personalized medical advice are beyond FDA's statutory authority." *Apter*, 80 F.4th at 588, 595. The Court explained that the "FDA is not a physician. It has authority to inform, announce, and apprise—but not to endorse, denounce, or advise." *Id.* at 595. Plaintiffs have therefore "plausibly alleged that FDA's [actions] fell on the wrong side of the line between telling *about* and telling *to,*" and thus Plaintiffs can "assert their *ultra vires* claims." *Id.*

On remand, the FDA asked to file a renewed motion to dismiss for lack of standing, citing a need to "account for the Fifth Circuit's opinion, which . . . affects the standing analysis." ECF.No.54, at 2.[4]

STANDARD OF REVIEW

"When standing is challenged on the basis of the pleadings," courts "must accept as true all material allegations of the complaint and construe the complaint in favor of the complaining party." *AAPS v. Tex. Med. Bd.*, 627 F.3d 547, 550 (5th Cir. 2010) (cleaned up). If the Defendant raises a factual dispute and "submits affidavits, testimony, or other evidentiary materials," the Plaintiff then "must prove the existence of subject-matter jurisdiction by a preponderance of the evidence" and may "submit facts through some evidentiary method to sustain his burden of proof." *Superior MRI Servs., Inc. v. All.*

[4] The FDA then used that opportunity to file over 350 pages of new material, expand its arguments, and raise factual disputes, none of which was affected by the Fifth Circuit's decision.

Healthcare Servs., Inc., 778 F.3d 502, 504 (5th Cir. 2015) (cleaned up). But Plaintiffs "are entitled to rely on the allegations in the Pleading if the evidence proffered by the defendant is immaterial because it does not contradict plausible allegations that are themselves sufficient to show standing." *Carter v. HealthPort Techs.*, LLC, 822 F.3d 47, 57 (2d Cir. 2016); *see Lane v. Halliburton*, 529 F.3d 548, 557 (5th Cir. 2008) ("[T]he court may find a plausible set of facts by considering any of the following: (1) the complaint alone; (2) the complaint supplemented by the undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." (cleaned up)).

SUMMARY OF THE ARGUMENT

Plaintiffs satisfy all three elements of standing. The undisputed allegations show that the Plaintiffs have suffered interference with their practice of medicine and the doctor-patient relationship, economic harm, reputational harm, and increased exposure to malpractice liability, all of which can be traced back to the FDA's campaign against ivermectin and would be remedied by equitable relief. Moreover, the record evidence shows it is more likely than not that Plaintiffs' disciplinary proceedings and forced resignations are traceable to the FDA's actions.

ARGUMENT

To establish standing to sue, as required by Article III of the U.S. Constitution, Plaintiffs must show (1) "a concrete and particularized injury," (2) "that is fairly traceable to the challenged conduct," and (3) "is likely to be redressed by a favorable judicial decision." *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013). Standing is not "a mechanical

exercise" and "incorporates concepts concededly not susceptible of precise definition." *Allen v. Wright*, 468 U.S. 737, 751 (1984). "[A]t least one plaintiff must have standing to sue." *Dep't of Com.*, 139 S. Ct. at 2565.

I. Plaintiffs Have Been Injured

Plaintiffs have demonstrated numerous injuries, any one of which is sufficient to establish standing. The injury "need not measure more than an identifiable trifle." *OCA-Greater Hous. v. Texas*, 867 F.3d 604, 612 (5th Cir. 2017) (cleaned up).

A. Interference in the Practice of Medicine

Plaintiffs have suffered injury to their practice of medicine. As accomplished physicians with many decades of experience, Plaintiffs have interests in practicing medicine according to their best reasoned judgment and in maintaining relationships of trust and confidence with their patients.

The doctor-patient relationship is privileged at law. *See, e.g.*, Tex. R. Evid. 509 ("Physician-Patient Privilege"). "[I]t is the physician's role to consider multiple factors, including a drug's FDA-approval status, to determine the best course of action for her patient," and the FDA injures that role when it interferes and offers medical advice. *United States v. Caronia*, 703 F.3d 149, 167 (2nd Cir. 2012) (citing *Buckman*, 531 U.S. at 350; 21 U.S.C. § 396); *cf. Trump v. IRAP*, 582 U.S. 571, 583 (2017) (interference with "a bona fide relationship" results in "concrete hardship"). If recreational and aesthetic injury are sufficient to establish standing, *see Friends of the Earth, Inc. v. Laidlaw Env't. Servs. (TOC), Inc.*, 528 U.S. 167, 183 (2000), then interference with a vocation and the doctor-patient relationship qualifies.

Congress is also "well positioned to identify intangible harms that meet minimum Article III requirements." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 341 (2016). Congress has recognized that doctors have an interest in being free from interference in their practice of medicine—especially from the FDA. *See* 21 U.S.C. § 396.[5]

The FDA argues this interference is all too "vague and conclusory" to support an injury, R-MTD.24, but Plaintiffs have pointed to specific harms resulting from that interference. Pharmacists have refused to fill ivermectin prescriptions from Dr. Apter for his patients, citing the FDA's actions regarding using the drug to treat COVID-19, which delays his ability to treat patients when early treatment is vital. Am.Compl. ¶¶ 14–16. In his extensive experience as a doctor, patients believe that the FDA's pronouncements are authoritative and want care that complies with such pronouncements. *Id.* ¶ 17. Insurance companies are also refusing to pay for ivermectin to treat COVID-19, and the only observable bases for this are pronouncements and pressure from the FDA. *Id.*

[5] Numerous courts have recognized that 21 U.S.C. § 396 is at least indicative that doctors have an interest in practicing medicine free from interference from the FDA, including the prescription of off-label drugs. *See, e.g., U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 (5th Cir. 2017); *Med. Mut. of Ohio v. AbbVie Inc.*, 784 F. App'x 457, 457 (7th Cir. 2019); *Markland v. Insys Therapeutics, Inc.*, 758 F. App'x 777, 780 (11th Cir. 2018); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 (2d Cir. 2016); *U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 454 n.2 (4th Cir. 2013); *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012); *United States v. Muoghalu*, 662 F.3d 908, 911 (7th Cir. 2011); *In re Gilead Sci. Sec. Litig.*, 536 F.3d 1049, 1051 & n.2 (9th Cir. 2008). This Court previously held that that § 396's application to drugs is not sufficiently clear to support "enlarg[ing] the scope of the *ultra-vires*-act exception to sovereign immunity," but acknowledged that "[i]n some circumstances, [that] may be a comfortable inference for the court to make." *Apter v. Dep't of Health & Hum. Servs.*, 644 F.Supp.3d 361, 369 (2022). The standing inquiry, which asks only whether a plaintiff has a "personal stake in the case," *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021) (cleaned up), is not subject to the clear statement rules that typically accompany sovereign immunity.

Pharmacists have similarly refused to fill Dr. Bowden's prescriptions for ivermectin, citing FDA directives not to use the drug for COVID-19. *Id.* ¶ 27. Her patients have also delayed seeking treatment for COVID-19, or been hesitant to accept her recommendations, because the FDA says not to use ivermectin for that purpose. *Id.* ¶ 29.

The FDA repeatedly insists that because Plaintiffs have continued to prescribe ivermectin, they have not been harmed. R-MTD.2, 17, 23–24, 28–29. But Plaintiffs' ability to prescribe ivermectin in *some* cases does not negate the many times the FDA's actions have interfered—and will continue to interfere—in others. *See, e.g.*, Am.Compl. ¶¶ 14–17, 25, 27–29, 40–43. It also does not account for the now-countless hours Plaintiffs have spent on the phone with pharmacists, or looking for new pharmacists, to get their prescriptions filled—time Plaintiffs could have spent with patients, as discussed below. Ex.29.

The FDA also argues that Plaintiffs cannot assert harm to third parties like their patients or outside pharmacists. R-MTD.24–26. But Plaintiffs do not need to rely on third-party harms because they suffered injury to their *own* practice of medicine due to their inhibited ability to treat patients, including prescribing and administering ivermectin. The Fifth Circuit has already concluded that the FDA exceeded its authority and crossed the line into interfering with the practice of medicine. *Apter*, 80 F.4th at 588–89, 595.

But the FDA is correct that its actions *also* harmed Plaintiffs' patients. Citing FDA directives, pharmacists refused to fill ivermectin prescriptions, preventing patients from being timely treated. Am.Compl. ¶¶ 27–28. And patients have delayed seeking effective COVID-19 care based on the FDA's statements, complicating treatment when early intervention is vital. *Id.* ¶ 15. Those patients, too, have an interest in ensuring the doctor-

patient relationship remains free from the FDA's meddling, and Plaintiffs can assert those interests under the traditional test for third-party standing. *See Singleton v. Wulff*, 428 U.S. 106, 114–115 (1976). "The closeness of the relationship" between Plaintiff physicians and their patients is obvious because a patient "cannot easily secure" ivermectin treatment "without the aid of a physician." *Id.* at 117. And patients seeking such treatment face "several obstacles" to asserting their own rights, including "imminent mootness"—a patient will no longer need ivermectin (which is most effective in the early stages of infection) before the suit completes—and "a desire to protect the . . . privacy" of the patient's wish for a treatment that has been widely disparaged. *Id.*

In arguing otherwise, the FDA ignores the unique considerations inherent in the practice of medicine that the Supreme Court has held can allow "providers to invoke the rights of their actual or potential patients," *June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103, 2118 (2020), especially regarding treatments that have been heavily stigmatized, in this case by the FDA as being animal-only drug forbidden for human use. The FDA blinks reality by claiming there is no reason those patients would be "unable or unwilling to bring claims on their own behalves." R-MTD.25 (quoting *AIDS Healthcare Found., Inc. v. City of Baton Rouge*, 2017 WL 2899689, at *4 (M.D. La. July 7, 2017)).

Plaintiffs' concrete injuries are confirmed by *TransUnion LLC v. Ramirez*, where the Supreme Court explained that "a 'close relationship' to a harm traditionally recognized as providing a basis for a lawsuit in American courts," or a "historical or common-law analogue for their asserted injury," is sufficient for purposes of standing. 594 U.S. 413, 417, 424 (2021) (quoting *Spokeo*, 578 U.S. at 340–41). An "exact duplicate" is not

required, thus allowing for "[v]arious intangible harms" and "'*de facto* injuries that were previously inadequate in law'" and "'may be difficult to prove or measure.'" *Id.* at 424–25, 437 (quoting *Spokeo*, 578 U.S. at 341) (emphasis removed)).

Tortious interference with the doctor-patient relationship is a cause of action at common law. *See, e.g.*, Phoebe Carter, *Liability for Interference with Physician-Patient Relationship*, 87 A.L.R. 4th 845 (1991) (collecting cases); *Regents of the Univ. of Cal. v. Aisen*, 2016 WL 1428072, at *6 (S.D. Cal. Apr. 12, 2016) (denying motion to dismiss claim for "tortious interference with the doctor-patient relations"); *Garcia v. Home Depot U.S.A., Inc.*, 1999 WL 362787, at *6 (N.D. Tex. June 2, 1999); *Moore & Assocs. v. Metro. Life Ins. Co.*, 604 S.W. 2d 487 (Tex. Civ. App. 1980). Generally, establishing injury for such claims requires showing that acts of the defendant disrupted an existing doctor-patient relationship, causing the plaintiff economic harm. *See, e.g.*, *Aisen*, 2016 WL 1428072, at *6–7. The injury experienced by Plaintiffs is not required to be "an exact duplicate," but it is analogous. *TransUnion*, 594 U.S. at 424–25, 437. As explained above, the FDA's actions interfered in Plaintiffs' relationships with their patients, causing patients to delay seeking treatment from Plaintiffs for COVID-19 and to hesitate to follow Plaintiffs' recommendations. Am.Compl. ¶¶ 28, 29. Plaintiffs were also required to divert hours that could have been spent with patients to respond to pharmacy inquiries and look for new pharmacists to fill prescriptions, causing economic harm, as discussed below. Ex.29. This is more than sufficient to establish injury under *TransUnion*.

B. Economic Harm

Plaintiffs have suffered economic harm. As the Fifth Circuit explained in *Alliance*

for Hippocratic Medicine v. FDA, Plaintiffs "sustain a concrete injury when they are forced to divert time and resources away from their regular" practice. 78 F.4th 210, 235–36 (5th Cir. 2023). Because pharmacists, citing the FDA's directives, have refused to fill Dr. Bowden's prescriptions for ivermectin, Dr. Bowden has been forced to spend countless hours on the phone with pharmacists and searching for alternative pharmacies to dispense the medication for her patients. Ex.29. She continues to have that experience multiple times each month. *Id.* Those hours could be devoted to her regular practice, including seeing additional patients. This diversion results in "economic harm . . . a quintessential Article III injury." *Alliance*, 78 F.4th at 235.

C. Increased Exposure to Malpractice Liability

The Fifth Circuit in *Alliance for Hippocratic Medicine* also held that plaintiffs "sustain a concrete injury" when a defendant's actions "expose them to greater [malpractice] liability and increased insurance costs." 78 F.4th at 236. The FDA's unlawful campaign exposes Plaintiffs to increased liability for their continued prescribing of ivermectin because courts have relied on the FDA's anti-ivermectin statements to determine "deviation from accepted medical practices," which "is an essential element of medical malpractice." *Staten Island Univ. Hosp.*, 157 N.Y.S.3d at 673; Am.Compl. ¶ 110.

D. Reputational Harm

Plaintiffs have suffered reputational harm. Under *TransUnion*, among the "[v]arious intangible harms" that suffice to establish concrete injury is "reputational harm," which "bears a 'close relationship' to . . . the tort of defamation." 594 U.S. at 417, 425, 432. It is beyond dispute that Plaintiffs have suffered reputational harm. Dr. Bowden in particular

has been subject to vicious reputational attacks and endured significant abuse online, examples of which are included in the Amended Complaint. Exs.23, 24.

In a notable example, a pharmacist using the TikTok handle "rx0rcist," with approximately 1 million followers on that platform, displayed the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and berated Dr. Bowden for using ivermectin because "the FDA said nope." Ex.23. Others have publicly labeled healthcare professionals who prescribe ivermectin as quack doctors practicing veterinary medicine on humans, specifically citing and showing a picture of Dr. Bowden. Ex.24. The FDA cannot divorce its medical recommendations and directives from the packing and "new engagement strategy" it used, Ex.20, which disparaged doctors who might be inclined to prescribe ivermectin to drive home the FDA's message that use of the drug for COVID-19 was inappropriate, if not forbidden.

E. Disciplinary Proceedings and Forced Resignations

Plaintiffs have been subject to disciplinary proceedings and forced to resign their various positions. Dr. Apter was referred by the Iowa Board of Medicine to the Washington Medical Commission and Arizona Medical Board because he prescribed ivermectin to treat COVID-19, and the referrals include copies of the FDA's publications directing against that use. Am.Compl. ¶ 18. Dr. Bowden was derided by Houston Methodist Hospital and forced to resign her privileges for prescribing ivermectin. *Id.* ¶ 21. And Dr. Marik was forced to resign from his positions at Eastern Virginia Medical School ("EVMS") and Sentara Norfolk General Hospital—even after developing EVMS's COVID-19 treatment protocol—for continuing to promote ivermectin to treat COVID-19 after the FDA's

attempts to stop use of those drugs for that purpose. *Id.* ¶¶ 38–39, 42.

The FDA argues that being subject to disciplinary proceedings is not a cognizable harm. R-MTD.18. But where "a plaintiff has engaged in a course of [protected] conduct and the state has instructed him to stop or face disciplinary action, . . . a plaintiff has adequately alleged a concrete and imminent harm sufficient to meet the 'injury in fact' requirement." *Kiser v. Reitz*, 765 F.3d 601, 608 (6th Cir. 2014). Dr. Apter may not be asserting a due process claim, but that says nothing about whether he's been injured in his time, money, and personal well-being because of the investigation.

The FDA now raises a factual challenge to the circumstances of Dr. Apter's disciplinary proceedings, as well as Dr. Bowen and Dr. Marik resignations. R-MTD.20–23. The FDA argues that "the referrals regarding Apter are not fairly traceable to the [FDA's] [s]tatements." R-MTD.21. But the FDA's new evidence shows otherwise. The complaint to the Washington Medical Commission was from a pharmacist charging "[i]nappropriate prescribing" because Dr. Apter wouldn't provide a "valid [non-COVID] medical reason" for the ivermectin prescription. R-MTD.Ex.B, at 3. The complaint cites the FDA's "recommendations" as the reason for the "increase[d] scrutiny." *Id.* And the referrals to the Washington Medical Commission and Arizona Medical Boards include copies of the FDA's directives. Ex.8.

The FDA also argues that Dr. Bowden and Dr. Marik "voluntarily resigned" from their hospital positions, so they weren't injured. R-MTD.2, 10–11, 14, 18, 21–23. That ignores the obvious fact that both Dr. Bowden and Dr. Marik resigned under duress. *See* Exs. 9, 10. Resignation under duress is a cognizable injury akin to termination. *See, e.g.*,

Green v. Brennan, 578 U.S. 547, 555 (2016) (discussing "constructive discharge").[6] The undeniable timing of these investigations and forced resignations immediately following when the FDA began its pressure campaign against ivermectin in earnest highlights the predominant role that issue played in the disciplinary actions.

II. Plaintiffs' Injuries Are Fairly Traceable to the FDA

"Proximate causation is not a requirement of Article III standing, which requires only that the plaintiff's injury be fairly traceable to the defendant's conduct." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 n.6 (2014). Traceability "'requires no more than *de facto* causality,'" *Dep't of Com.*, 139 S. Ct. at 2566 (quoting *Block v. Meese*, 793 F.2d 1303, 1309 (D.C. Cir. 1986)).

An injury is also "fairly traceable" if it "relies . . . on the predictable effect of Government action on the decisions of third parties," even when those decisions are illogical or "unlawful." *Dep't of Com.*, 139 S. Ct. at 2565–66; *see Tozzi v. HHS*, 271 F.3d 301, 308–09 (D.C. Cir. 2001); *Cmty. For Creative Non–Violence v. Pierce,* 814 F.2d 663, 669 (D.C. Cir. 1987) (finding traceability if government action played a "substantial factor motivating the third parties' actions"). "[P]redictability does not require certainty." *Missouri v. Biden*, 83 F.4th 350, 371 (5th Cir. 2023).

The FDA is the common thread through all of Plaintiffs' injuries, which began only after the FDA embarked on its campaign to stop the use of ivermectin for COVID-19 and

[6] Dr. Marik's public reflection that resigning "was not an easy decision to make, but [he] felt it was time to focus [his] attention and energy to other interests," R-MTD.Ex.O, says nothing about whether his resignation was free from duress. *See* R-MTD.22.

which often involve explicit invocation of the FDA's directives and recommendations. The agency has consistently asserted itself as the authoritative voice on drugs in the United States, and now leverages its influence in an admittedly novel way to hang Damocles' sword over healthcare professionals and pressure both professional and patient judgment about the use of ivermectin. *See* Ex.20 (FDA celebrating this "new engagement strategy").

The FDA has already conceded that its actions "influenced the thinking" of third parties about the "use of ivermectin to prevent or treat COVID-19," and those third parties then "allegedly took actions that caused Plaintiffs' injuries." ECF.No.25, at 15. But the FDA expresses disbelief that this simple chain of events was predictable.

Common sense dictates that there was no reason for the FDA's actions to stop the use of ivermectin *except* to cause such reactions. The FDA told the entire country to "Stop it" and "Stop it with the #Ivermectin," with the tweet being the most-viewed in FDA history, so the FDA cannot now insist that it is not even *plausible* that patients, pharmacists, professional groups, medical boards, and hospitals may have reacted by doing just that.

The FDA even sent a letter about ivermectin to the Federation of State Medical Boards and the National Association of Boards of Pharmacy linking to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." Ex.22. Combined with the FDA's public pressure campaign telling people to "Stop it with the #Ivermectin," it was predictable and intended that those regulatory boards—who obviously want to stay in the good graces of a federal regulatory body—would react by focusing their attention on doctors seeking to use ivermectin.

And even if any of these reactions weren't immediately predictable, they definitely

were shortly after the FDA began its campaign. But the FDA not only celebrated its success, Ex.20, it has consistently maintained "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," at least one of its FAQs, and its social media posts on official FDA platforms, and it even doubled down on April 26, 2022, Ex.7.

The FDA asserts that all Plaintiffs' injuries were caused by independent third parties because, quoting *Bennett v. Spear,* 520 U.S. 154, 169 (1997), the FDA's actions lacked "'determinative or coercive effect.'" R-MTD.18–19. This misdirection attempts to import the standard for final agency action under the APA. *Id.* The Fifth Circuit has already rejected the FDA's attempt to import the requirements for final agency action into the question of sovereign immunity. *See Apter*, 80 F.4th at 591. All that matters here is whether the injury is "fairly traceable" to the FDA.[7]

The undisputed allegations and evidence in the record shows that Plaintiffs' injuries are "fairly traceable" to the FDA's directives against the use of ivermectin for COVID-19. Pharmacists cited the FDA's "recommendations" in refusing to fill ivermectin for Dr. Apter's and Dr. Bowden's patients. Am.Compl. ¶¶ 15, 27–28; Exs. 8, 9; *see also* R-MTD.Ex.B, at 3 (pharmacy flagging, and declining to fill, ivermectin prescription based on "recommendations from . . . FDA"); R-MTD.Ex.C, at 3-4 (pharmacist directed to "scrutinize the [ivermectin] prescription because of recommendations from . . . the FDA"). As a result, Dr. Apter and Dr. Bowden spent countless hours justifying their prescriptions

[7] The FDA's citation to *Physicians for Integrity in Medical Research, Inc. v. Ostroff*, 670 F. App'x 450, 451 (9th Cir. 2016) (mem.), is unpersuasive. That out-of-circuit, unpublished opinion does not address ultra vires FDA actions intentionally designed to "engag[e]" the public, Ex.20, give medical advice, and sway private and professional behavior.

and seeking pharmacies to fill them. Ex.29; *see also* R-MTD.Ex.B, at 4 (Dr. Apter responding to pharmacy call); R-MTD.Ex.C, at 3 (same). And Plaintiffs have been subject to vicious reputational attacks and online abuse, which have referenced the FDA's statements and tweets for support because "The FDA said nope." Exs.23, 24.

That medical boards and hospitals have cited additional justification for their actions, R-MTD.8–13, 20–23, does not break their traceability to the FDA. *See Rieves v. Town of Smyrna,* 67 F.4th 856, 862 (6th Cir. 2023) ("[T]he plaintiff need not prove that the defendant was the sole cause of his injury[.]"); *Sierra Club v. Dep't of Interior*, 899 F.3d 260, 284 (4th Cir. 2018) (similar). To the contrary, those actions *explicitly* invoke the FDA, most often "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." As explained above, the complaints and referrals that instigated the proceedings explicitly referenced the FDA's recommendations and directives. Dr. Bowden's resignation was spurred in part by public statements by hospital leadership that she was "spreading 'dangerous' misinformation" about COVID-19 treatments, i.e. ivermectin, R-MTD.Ex.L, at 3–4, and the hospital had earlier made clear that its stance was based in part on the FDA's statements. Ex.30, Houston Methodist Hospital, *5 Reasons You Shouldn't Take Ivermectin for COVID-19* (Sept. 10, 2021), http://tinyurl.com/25mry88t (linking to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19"). And Sentara Norfolk General Hospital's decision to prohibit the use of ivermectin for COVID-19, which precipitated Dr. Marik's resignation, Ex.10, was prompted not "'primarily' . . . [by] clinical trials" data, R-MTD.22, but by the joint statement of the AMA, APhA, and ASHP, which itself relies on "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *See* R-MTD.Ex.N,

at 135 ("When our team saw [the joint statement] . . . we felt it was our duty" to "stop prescribing and using ivermectin[.]"). The FDA's actions directly harmed Plaintiffs or predictably set into motion the events that did.

The FDA excuses its actions because they "'neither require nor forbid any action.'" R-MTD.19 (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 493–94 (2009)). The Fifth Circuit has already rejected this argument, holding that the FDA used "syntax that is imperative rather than declaratory." *Apter*, 80 F.4th at 588. Despite the FDA's unceasing attempts to characterize its actions as merely informational, the Fifth Circuit was clear that the FDA used "imperative" language and went "beyond mere factual communication." *Apter*, 80 F.4th at 591.

The FDA claims that "[n]one of the Statements recommended or instructed doctors not to prescribe ivermectin products to prevent or treat COVID-19 or pharmacies not to fill prescriptions for ivermectin." R-MTD.5. The FDA similarly asserts that its directives only "generally recommended to *consumers* . . . that they should not take ivermectin to prevent or treat COVID-19." R-MTD.19. This ignores that the FDA did in fact send a letter about ivermectin to the Federation of State Medical Boards and the National Association of Boards of Pharmacy, linking to "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," betraying the assertion it was only for consumers. Ex.22. The FDA also ignores its public pressure campaign telling the public to "Stop it" and "Stop it with the #Ivermectin." The FDA directed its message to *everyone*, so it's entirely foreseeable when *anyone* listened. These arguments are also beside the point because Plaintiffs have been injured in their ability to practice medicine and in their relationship with patients, who

unquestionably are consumers to whom the FDA alleges its campaign was addressed.

The FDA also relies on myriad language buried in some of its documents that "'[i]f your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed.'" R-MTD.20. But that statement was not included in the social media posts, for example, and in any event the Fifth Circuit has already held that "the trailing qualifier does not lessen the opening instruction's imperative character." *Apter*, 80 F.4th at 589. When such statements fall under a title of "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19," or follow "Q: Should I take ivermectin to prevent or treat COVID-19? A: No," they convey the message that ivermectin should be taken as prescribed only when doctors prescribe the drug *for purposes other than COVID-19*. Indeed, that was explicit in the first draft of the publication, which told patients to follow ivermectin prescriptions only "for an FDA-approved use." Ex.19, at 2. Moreover, Defendants cannot justify an unlawful foray into the practice of medicine with a few subsequent, ambiguous statements, especially when its actions are viewed as a whole.

Further fatal to the FDA's argument, traceability can also be established in retrospect. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992) ("[P]laintiffs [can] adduce facts showing that [third-party] choices *have been* or will be made in such manner as to produce causation and permit redressability of injury[.]" (emphasis added)). As explained above, Pharmacists have expressly cited FDA directives in refusing to fill Dr. Bowden's prescriptions for ivermectin. Am.Compl. ¶ 27. Her patients have delayed seeking treatment because the FDA says not to use ivermectin to treat COVID-19. Am.Compl. ¶ 29. And Dr.

Apter is currently subject to state regulatory board proceedings, which were instigated in reliance on the FDA's statements at issue here. R-MTD.Ex.D.

Courts have also relied on the FDA's actions, citing the FDA's statements as evidence about the effectiveness of ivermectin to treat COVID-19 and the appropriate standard of care. *See, e.g.*, *Smith*, 2021 WL 4129083, at *1, 2, 4; *DeMarco*, 263 A.3d at 435; *Abbinanti*, 2021 IL App (2d) 210763, ¶ 10. Indeed, courts have looked to the FDA's "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" to determine "deviation from accepted medical practices," which "is an essential element of medical malpractice." *Staten Island Univ. Hosp.*, 157 N.Y.S.3d at 672–73. While the Fifth Circuit held that the FDA did not impose a "legal standard," *Apter*, 80 F.4th at 594, the FDA's actions have nonetheless increased Plaintiffs' exposure to legal liability.

It is thus more than "fair" to conclude that Defendants' statements on ivermectin are "traceable" to the harm suffered by Plaintiffs. Indeed, leading healthcare professionals, scientists, and researchers recognize that the FDA is interfering with the practice of medicine vis-à-vis ivermectin. *See* Am.Compl. ¶¶ 111–14. For example, Peter A. McCullough, M.D., MPH—a renowned epidemiologist—explained that "[t]he FDA put official communications out through Twitter and through other social media, and major media. And it said, 'Ivermectin is only a horse dewormer. Don't use a veterinary product to treat COVID-19.'" Am.Compl. ¶ 112. He concluded, "So, there was a clear theme that was going on. At least the obvious suppression from a regulatory . . . perspective." *Id.* Pierre Kory, M.D., MPA—a distinguished and highly published critical care specialist—has made similar observations. *See* Am.Compl. ¶ 114.

Members of Congress likewise recognize the FDA is illegally interfering with the practice of medicine by "tak[ing] steps to curtail the use of potential early treatments," including through the FDA's "mocking of ivermectin, conflating a widely-available human drug that was the basis for Nobel prize winning research, with its veterinary version," and have "created a new industry standard that restricts doctors' abilities to prescribe certain off-label treatments for COVID-19." Ex.28, at 2–3. The Members also cite "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." *Id.* at 3 n.11.

When the actions of third parties consistently cite to the same FDA directives, Plaintiffs' injuries do not turn on "guesswork as to how independent decisionmakers will exercise their judgment." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 413 (2013). Rather, the link is at least "fair," if not undeniable. The FDA would have the Court believe that all these other actions—which explicitly rely on the FDA—would have occurred even absent the FDA's directives and recommendations, but *that* is the implausible view.

III. Plaintiffs' Injuries Are Redressable

Plaintiffs "need only show that a favorable ruling could potentially lessen [their] injury," and they "need not definitively demonstrate that a victory would completely remedy the harm." *Sanchez v. R.G.L.*, 761 F.3d 495, 506 (5th Cir. 2014) (cleaned up); *see also Friends of the Earth*, 528 U.S. at 181 (plaintiff meets the redressability test if it is "likely"—not certain—"that the injury will be redressed by a favorable decision").

"Causal connection and redressability are two sides of the same coin." *Animal Legal Def. Fund v. Veneman*, 469 F.3d 826, 835 (9th Cir. 2006). Thus, because Plaintiffs harms are fairly traceable to the FDA's actions, redressability is presumed. The FDA would not

have issued the challenged statements if it did not believe its actions would affect the use of ivermectin for COVID-19. Having succeeded in its campaign, the FDA cannot now disclaim that clearly intended effect, nor contend that vacating the challenged statements would somehow be fruitless. The FDA's actions have inhibited Plaintiffs' ability to practice medicine, and thus a favorable ruling would result in at least partial relief by removing that justification for the inhibition and the source of the reputational sting.

Here, the judgment of healthcare professionals and other entities in the causal chain of Plaintiffs' injuries would be freed from this material interference. For decades, healthcare professionals, hospitals, and state regulatory boards have supported (i.e., not interfered with) off-label prescriptions and would likely revert toward that norm (which is sufficient for redressability). Am.Compl. ¶¶ 61–66, 124. Patients also will no longer be caught between the FDA's pressure campaign and Plaintiffs' advice, restoring the primacy of the doctor-patient relationship. Am.Compl. ¶¶ 16, 24, 27.

The FDA argues that intervention by this Court "would not likely cause sophisticated actors in the healthcare field" to change course, because of their "independent scientific knowledge about the therapeutic risks and benefits of using ivermectin to prevent or treat COVID-19." R-MTD.2, 27. The FDA ignores that the third parties here repeatedly point *to the FDA*. The FDA touts that the AMA, APhA, and ASHP take the same position, but *they too cite the FDA*. Ex.25. The FDA's deference to Merck, R-MTD.27–28, is particularly unpersuasive because it presumes representations by a pharmaceutical company (which was in the process of developing a competing drug) carry as much weight as the FDA. Plaintiffs also allege interference with their doctor-patient relationships, and

the FDA makes no argument that patients are sophisticated actors in the sense used here.

The Fifth Circuit has also held that redressability is satisfied where the "fear of future prosecution may be alleviated" by a favorable ruling, especially where it could "arguably" result in "third parties" "chang[ing] . . . the policy" that negatively affects Plaintiffs. *McClure v. Ashcroft*, 335 F.3d 404, 411 (5th Cir. 2003). It seems implausible that courts will continue to rely on the FDA's advice to establish the standard of care if it is declared unlawful and enjoined. *Cf. Staten Island Univ. Hosp.*, 157 N.Y.S.3d at 673.

The FDA also argues that because the Fifth Circuit held the FDA's statements have no legal effect, Plaintiffs can obtain no other relief. R-MTD.29. But Plaintiffs seek other equitable relief that would require the FDA either to take down its still-posted statements or amend them. Am.Compl.43–44. If this Court issued a ruling requiring those additional forms of relief, it would "potentially lessen" Plaintiffs' injuries. *Sanchez*, 761 F.3d at 506.

In sum, the FDA dismisses any consequences of the requested relief as "'speculative.'" R-MTD.28. But decades of consistent medical practice, and observation of the pervasive off-label prescription of drugs throughout medicine, establish a compelling baseline that would be at least partially restored once the FDA ceases its unlawful interference, and the potential of even partial relief is sufficient to withstand a motion to dismiss. *Id.*

CONCLUSION

The Court should deny Defendants' motion to dismiss.

January 12, 2024

/s/ Jared M. Kelson

R. Trent McCotter
So. Dist. No. 3712529
Texas Bar No. 24134174
Michael Buschbacher (*pro hac vice*)
D.C. Bar No. 1048432
Jared M. Kelson (*pro hac vice*)
Attorney-In-Charge
D.C. Bar No. 241393
Laura B. Ruppalt
V.A. Bar No. 97202
Boyden Gray PLLC
801 17th St NW, Suite 350
Washington, DC 20006
(202) 706-5488
jkelson@boydengray.com

CERTIFICATE OF WORD AND PAGE COUNTS

I hereby certify that the total number of words in this document, exclusive of those sections designated for omission, is 8738 words, as registered by Microsoft Word. I further certify that this document, exclusive of those sections designated for omission for word limit purposes, is 30 pages. I further certify that this document is in size 13 Times New Roman font.

/s/ Jared M. Kelson
Jared M. Kelson

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

/s/ Jared M. Kelson
Jared M. Kelson